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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/052,942	01/23/2002	Maurice Zauderer	1821.0090004	1028

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STERNE, KESSLER, GOLDSTEIN & FOX PLLC
1100 NEW YORK AVENUE, N.W.
WASHINGTON, DC 20005

EXAMINER	
EPPERSON, JON D	

ART UNIT	PAPER NUMBER
1639	

DATE MAILED: 10/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/052,942	ZAUDERER ET AL.	
	Examiner	Art Unit	
	Jon D Epperson	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 July 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-84* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-84* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

SUBSTITUTE RESTRICTION

Please note: There is a change in Examiner handling prosecution in this case from Padmashri Ponnaluri to Jon Epperson.

1. The Response to the Restriction Requirement filed on May 28, 2004, is acknowledged.

2. Upon further review of Applicants' arguments, all previous restriction and/or election of species requirements are hereby withdrawn and a new substitute restriction and/or election of species is now required (see below).

Election/Restriction

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-45, 48-65, 69-80 drawn to a method for "screening" a library of "immunoglobulins" by "selecting polynucleotides which encode an antigen-specific immunoglobulin molecule", classified variously in class 435, subclass 7.1, 7.2, DIG 6.

II. Claims 46-47 drawn to a method for "producing" a library of "oligonucleotides", classified variously in class 435, subclass 6, DIG 47.

III. Claims 66 and 81-82, drawn to a kit, classified variously in class 436, subclass 808; class 435, subclass 975.

IV. Claims 67 and 83, drawn to an antibody, classified in class 530, subclass 387.1+.

V. Claims 68 and 84, drawn to a composition, classified variously in class 424, subclass 464+, class 424, subclass 130.1+.

4. The inventions are distinct, each from the other because of the following reasons:

5. Groups I-V represent separate and patentably distinct inventions. Groups I-II are drawn to different methods and Groups III-V are drawn to different products and/or kits (i.e., e.g., which are directed to different purposes, use different materials, recite different method or process steps for the preparation of different product(s), screening of different characteristics, such as different binding affinities, different biochemical reaction conditions, etc. or lead to different final results). Therefore, the groups that describe these products and methods have different issues regarding patentability and enablement, and represent patentably distinct subject matter, which merits separate and burdensome searches. Art anticipating or rendering obvious each of the above-identified groups respectively would not necessarily anticipate or render obvious another group, because they are drawn to different inventions that have different distinguishing

6. Groups I and II represent separate and patentably distinct methods. The methods are distinct because they use different steps, require different reagents and/or will produce different results. In this case, the method of Group II employs is drawn to a method of "producing" a library of "polynucleotides" using a virus vector, whereas Group I is drawn to a method of "screening" an expression library of "antibodies." As a result, Group I requires a different reagent (e.g., polypeptides) that are not required by Group I. In addition, since Group II does not require an antigen and, as a result, the Groups will produce different results i.e., peptide

screening versus nucleic acid production. Therefore, Groups I and II have different issues regarding patentability and enablement and represent patentably distinct subject matter.

7. Likewise, Groups IV and V represent patentably distinct products. Groups IV and V represent separate and patentably distinct products because they differ in respect to their properties, their use and the synthetic methodology for making them. For example, Group V requires "a pharmaceutically acceptable carrier", which is not required by Group IV. Furthermore, Group IV can be used for different purposes than Group V e.g., screening methods. Therefore, art anticipating or rendering obvious each of the above-identified groups respectively would not necessarily anticipate or render obvious another group, because they are drawn to different inventions that have different distinguishing features and/or characteristics. Consequently, Groups IV and V have different issues regarding patentability and enablement and represent patentably distinct subject matter.

8. In addition, Groups III and IV-V represent separate and distinct products. They differ in respect to their properties, their use and the synthetic methodology for making them. In the instant case, Group III refers to a plurality of articles grouped together to form a "kit", whereas Groups IV-V refers to only a single article or an article with a pharmaceutically acceptable carrier. These Groups also have different purposes e.g., the kit can be used for screening whereas the pharmaceutical composition is used for treating health problems. Therefore, Groups III and IV-V have different issues regarding patentability and enablement and represent patentably distinct subject matter.

9. Finally, if the applicant argues that Groups I and IV are somehow related as process of making and product made, the inventions can be considered to be distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different products or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, (2) the product as claimed can be made by another materially different process e.g., transgenic mice, bacteriophage display, virus without tri-molecular recombination, solid-phase synthesis, computer design.

10. These inventions have acquired a separate status in the art as shown by their different classification and/or divergent subject matter. The different methods and products would require completely different searches in both the patent and non-patent databases, and there is no expectation that the searches would be coextensive. Therefore, this does create an undue search burden, and restriction for examination purposes as indicated is proper.

Species Election

11. This application contains claims directed to patentably distinct species of the claimed invention for Groups I-V. Election is required as follows.

12. If applicant elects the invention of Group I, applicant is required to elect from the following patentably distinct species. Claim 1 is generic.

Subgroup 1: Species of host cells (e.g., see claim 1)

Applicant must elect, for the purposes of search, a ***single species*** of host cells e.g., HeLa cells. Please also indicate whether the elected host cells are permissive for the production of infectious viral particles (e.g., see claim 35).

Subgroup 2: Species of immunoglobulin source (e.g., see claims 1, 9)

Applicant must elect, for the purposes of search, a ***single species*** of immunoglobulin source (e.g., human).

Subgroup 3: Species of intracellular immunoglobulin for "first" and "second" libraries (e.g., see claims 1, 4 and 69)

Applicant must elect, for the purposes of search, a ***single species*** of immunoglobulin for both the "first" library and "second" library (if present) including the class of antibody (e.g., IgM) and the physical makeup (e.g., see figure 13a wherein VH-CH1-TM-DD is disclosed). Applicants must further indicate whether or not said intracellular immunoglobulins are "single-chain" immunoglobulins (i.e., yes or no, see claim 69).

Subgroup 4: Species of "first" and "second" library construction (e.g., see claims 1, 37, 37)

Applicant must elect, for the purposes of search, a ***single species*** of "first" library construction and "second" library construction if present (e.g., introduced via a eukaryotic virus vector, see claim 18). Please specify the actual virus (e.g., see claim 34 wherein vaccinia virus is disclosed). Please also indicate whether the virus is attenuated (e.g., see claim 36). Please also indicate whether the virus is deficient in D4R synthesis (e.g., see claim 37). Please also indicate the type of genome e.g., linear, double-stranded (e.g., see claim 29). Please also indicate whether said virus is an animal virus (e.g., see claim 24). Please also indicate whether said virus is RNA or DNA and linear or double stranded (e.g., see claims 27-29).

Subgroup 5: Species of promoter (e.g., see claims 46-47)

Applicant must elect, for the purposes of search, a ***single species*** of promoter e.g., vaccinia virus p7.5 promoter (e.g., see claim 42). Please also indicate whether the promoter is a synthetic early/late promoter and whether it is constitutive (e.g., see claims 43, 41). Applicants must also indicate whether or not said promoter is "associated" with a suicide gene (e.g., see claim 50). Applicants must also indicate whether said promoter if non-constitutive is differentiation-induced, cell type-restricted, etc. (e.g., see claim 51).

Subgroup 6: Species of transcriptional control region (e.g., see claims 44)

Applicant must elect, for the purposes of search, a ***single species*** of transcriptional control region e.g., T7 RNA polymerase (e.g., see claim 44). Applicants must also indicate whether said transcriptional control functions in the cytoplasm or nucleus (e.g., see claim 38). Applicants must further whether said transcriptional control region comprises a termination region (e.g., see claim 45).

Subgroup 7: Species of phenotype (e.g., see claims 48-49, 55)

Applicant must elect, for the purposes of search, a ***single species*** of phenotype (e.g., non-adherence due to an inhibition of an essential function by said intracellular immunoglobulin molecule, see claims 48-49; see also claim 55 wherein "reduced expression of said cell surface antigen is disclosed, see also claim 57 wherein "altered susceptibility to an infectious agent is disclosed; see also claim 58 wherein "altered drug sensitivity is disclosed", etc.).

Subgroup 8: Species of heterologous peptide if present (e.g., see claims 61, 65)

Applicant must elect, for the purposes of search, a ***single species*** of heterologous peptide if present (e.g., fused targeting sequence, epitope tag, 6-His tag etc.). Applicants must also indicate whether said target sequence is capable of localizing to the "golgi", or "endoplasmic reticulum", etc. (e.g., see claim 62). If Applicants elect an epitope tag, Applicants must fruther specify the type e.g., myc, BSP, etc. (e.g., see claim 64).

13. If applicant elects the invention of Group II, applicant is required to elect from the following patentably distinct species. Claim 46 is generic.

Subgroup 1: Species host cell (e.g., see claims 46, 47)

Applicant must elect, for the purposes of search, a ***single species*** of host cell e.g., HeLa.

Subgroup 2: Species of eukaryotic virus vector (e.g., see claims 46, 47)

Applicant must elect, for the purposes of search, a ***single species*** of eukaryotic virus vector. Please specify the actual virus used (e.g., vaccinia virus, see above). Please also indicate whether it is an "animal" virus, capable of producing infectious viral particles in mammalian cells, the type of genome e.g., linear, double-stranded DNA, whether the virus is attenuated and whether the virus is deficient in D4R synthesis (e.g., see above).

Subgroup 3: Species of transfer plasmids (e.g., see claims 46, 47)

Applicant must elect, for the purposes of search, a ***single species*** of host cell e.g., specify type including whether or not it has a vaccina promoter and also any relevant non essetial virus sequences e.g., poxvirus.

Subgroup 4: Species of immunoglobulin source (e.g., see claims 46, 47)

Applicant must elect, for the purposes of search, a ***single species*** of immunoglobulin source e.g., human.

Subgroup 5: Species of immunoglobulin (see claims 46, 47)

immunoglobulin for both the first and second libraries including the class of antibody (e.g., IgM) and the physical makeup (e.g., see figure 13(a) wherein VH-CH1-TM-DD is disclosed).

14. If applicant elects the invention of Group III, applicant is required to elect from the following patentably distinct species. Claim 66 is generic.

Subgroup 1: Species host cell (e.g., see claims 66)

Applicant must elect, for the purposes of search, a ***single species*** of host cell e.g., HeLa, COS.

Subgroup 2: Species of library (e.g., see claims 66)

Applicant must elect, for the purposes of search, a ***single species*** of first library (e.g., see Group I, subgroup 4 above).

Subgroup 3: Species of immunoglobulin subunit (e.g., see claims 66)

Applicant must elect, for the purposes of search, a ***single species*** of immunoglobulin subunit (e.g., see Group I, subgroup 3 above).

Subgroup 4: Species of phenotype (e.g., see claim 66)

Applicant must elect, for the purposes of search, a ***single species*** of phenotype (e.g., non-adherence due to an inhibition of an essential function by said intracellular immunoglobulin molecule, see claims 48-49; see also claim 55 wherein "reduced expression of said cell surface antigen is disclosed, see also claim 57 wherein "altered

susceptibility to an infectious agent is disclosed; see also claim 58 wherein "altered drug sensitivity is disclosed", etc.).

Subgroup 5: Species of heterologous peptide if present (e.g., see claim 66)

Applicant must elect, for the purposes of search, a ***single species*** of heterologous peptide if present (e.g., fused targeting sequence, epitope tag, 6-His tag etc.). Applicants must also indicate whether said target sequence is capable of localizing to the "golgi", or "endoplasmic reticulum", etc. (e.g., see claim 62). If Applicants elect an epitope tag, Applicants must fruther specify the type e.g., myc, BSP, etc. (e.g., see claim 64).

15. If applicant elects the invention of Group IV-V, applicant is required to elect from the following patentably distinct species. Claims 81 and 82 are generic for Groups IV and V, respectively.

Subgroup 1: Species antibody (e.g., see claim 81)

Applicant must elect, for the purposes of search, a ***single species*** of antibody i.e., provide Sequence ID NO to which Applicant will be restricted to as a group. Please note that each antibody constitutes its own group and is not a "species election" for purposes of search.

Subgroup 2: Species of carrier (e.g., see claim 82)

If Applicant elects Group V, Applicant must further elect a ***single species*** of carrier.

16. **Please Note:** Applicants must disclose which claims read on the elected species (see paragraphs 20 and 21 below).

17. The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made. For different species of method, the method steps for each species would differ.

Moreover, the above species can be separately classified. Consequently, the species have different issues regarding patentability and represent patentably distinct subject matter. Therefore, this does create an undue search burden, and election for examination purposes as indicated is proper.

18. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

19. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a a rejection under 35 U.S.C. 103(a) of the other invention.

20. Applicant is advised that a reply to this requirement ***must include an identification of the species that is elected consonant with this requirement***, ***and a listing of all claims readable thereon, including any claims subsequently added***. An argument that a claim is allowable or that all claims are generic is considered ***nonresponsive*** unless accompanied by an election.

21. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the

limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, ***applicant must indicate which are readable upon the elected species***. MPEP § 809.02(a).

22. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.43). Because the above restriction/election requirement is complex, a telephone call to applicants to request an oral election was not made. See MPEP § 812.01.

23. Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

24. Applicant is also reminded that a 1 – month (not less than 30 days) shortened statutory period will be set for response when a written requirement is made without an action on the merits. This period may be extended under the provisions of 37 CFR 1.136(a). Such action will not be an "action on the merits" for purposes of the second action final program, see MPEP 809.02(a).

25. Finally, Applicant is reminded that where applicant elects claims directed to a product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon D Epperson whose telephone number is (571) 272-0808. The examiner can normally be reached Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jon D. Epperson, Ph.D.
October 1, 2004